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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,761	02/21/2006	Takamasa Watanabe	20320155PUS1	6669

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
08/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,761	WATANABE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1.Applicant's amendment, filed on 6/30/06, is acknowledged.

2. Claims 19-30 are pending.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 19-20, drawn to a method for preventing, improving or treating of inflammatory bowel disease (IBD), comprising administering a therapeutic agent comprising an effective amount of anti-CD81 antibody to a mammal in need thereof.

II. Claim 21, drawn to a method for screening a substance as an active ingredient for preventing, improving or treating IBD, comprising: (a) contacting cells capable of expressing CD81 gene with a test substance, (b) measuring an amount of CD81 gene expression in the cells contacted with the test substance, and comparing the amount with an amount of the corresponding gene expression in control cells not contacted with the test substance, and (c) selecting the test substance reducing the amount of CD81 gene expression on the basis of the comparison results in (b).

III. Claims 22, drawn to a method for screening a substance as an active ingredient for preventing, improving or treating IBD, comprising: (a) contacting cells capable of expressing CD81 with a test substance, (b) measuring an expression amount of CD81 in the cells contacted with the test substance, and comparing the expression amount with an expression amount of the protein in control cells not contacted with the test substance, and (c) selecting the test substance reducing the expression amount of CD81 on the basis of the comparison results in (b).

IV. Claim 23, drawn to a method for screening a substance as an active ingredient for preventing, improving or treating IBD, comprising: (a) contacting a test substance with CD81, (b) measuring function (activity) of CD81 after contact with the test substance, and comparing the function (activity) with function (activity) of CD81 not contacted with the test substance, and (c) selecting the test substance inhibiting the function (activity) of CD81 on the basis of the comparison results in (b).

V. Claims 24-25, drawn to a disease marker for IBD, which comprises a polynucleotide having at least 15 continuous bases in the base sequence of a CD81 gene or a polynucleotide complementary thereto.

VI. Claims 26-27, drawn to a method for diagnosing IBD, which comprises: (a) binding a RNA prepared from a biopsy of a subject or a complementary polynucleotide transcribed therefrom to the disease marker of claim 24 or, (b) measuring the amount of CD81 RNA derived from the biopsy using the disease marker as an index, and (c) diagnosing IBD on the basis of the measurement results in (b).

VII. Claim 28, drawn to a disease marker for IBD comprising an antibody which recognizes CD81.

VIII. Claims 29-30, drawn to a method for diagnosing IBD, which comprises: (a) binding a protein prepared from a biopsy of a subject to the disease marker of claim 28, (b) measuring the protein derived from the biopsy bound to the disease marker using the disease marker as an index, and (c) diagnosing IBD on the basis of the measurement results in (b).

5. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group V was found to have no special technical feature that defined the contribution over the prior art of US 20030113914 (see entire document).

The '914 publication teaches probes and primers to human CD81 were designed to hybridize to a human CD81 sequence, using published sequence information. For human CD81 the PCR primers were: forward primer: CAGATCGCCAAGGATGTGAA (see published SEQ ID NO: 4) reverse primer: GCGTTGTTGGCGTCATCA (See published SEQ ID NO: 5) (see 256¶ and published claims 1-20 in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 3, 2007

Maher Haddad

Maher Haddad, Ph.D.
Primary Patent Examiner
Technology Center 1600